GMB OPERATIONS MANUAL
Chapter - Pre-Award Process
Section - Human Subjects

DATE: May 17, 1999

SUBJECT: Review of Applications and Award of Grants/Cooperative Agreements Involving Human Subjects

PURPOSE: This document sets forth procedures relating to implementation of the human subjects* regulations. Except for research that is exempt (see below), these procedures are applicable to all CDC grant*** applications and awards in which human subjects (as defined below) are involved.**

* The words "subjects" and "participants" are used interchangeably in this document.
** References to CDC also apply to ATSDR.
***References to grants apply to cooperative agreements.

Exempt Research Categories

Note: The exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners, fetuses, pregnant women, or human in vitro fertilization, Subparts B and C.

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

> **Note**: The above exemption of research involving survey or interview procedures or observation of public behavior, does not apply to research with children except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

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1. Code of Federal Regulations, Title 45 Part 46, as amended

2. PHS Grants Administration Manual, Chapter 1-07, Protection of Human Subjects.

3. Multiple Project Assurance List (M.P.A.L.) of institutions pledging compliance with DHHS regulations. (Issued periodically by the Office for Protection from Research Risks.)

4. OPRR 1993 Protecting Human Research Subjects Institutional Review Board Guidebook.

5. CDC Procedures for Protection of Human Research Participants

6. Policies and Procedures for Protecting Human Research Participants in CDC-Funded Research (1999)

Definitions

1. Institution - any public or private entity or agency (including Federal, State, and other agencies).

2. Human Subject - a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information (e.g., medical records, employment records, or school records).

3. Legally Authorized Representative - an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the research.

4. Informed Consent - the legally effective informed consent of the human subject or the subject's legally authorized representative, so situated as to allow sufficient opportunity to consider whether to participate and to minimize the possibility of coercion or undue influence.

5. Institutional Assurance - the documentation on file with (or submitted when requested

by) the Office for Protection from Research Risks (OPRR), National Institutes of Health, from a grantee or a prospective grantee, assuring institutional compliance with implementation of regulations for the protection of human research subjects.

6. Institutional Review Board (IRB) - a board or committee charged with responsibility for review of research activities involving human subjects conducted at or sponsored by the institution. The composition of the IRB and details of its procedures and responsibilities are specified in 45 CFR 46 and included in the institutional assurances as approved by OPRR.

7. Certification - official notification by the institution to Department of Health and Human Services (DHHS) in accordance with the requirements of 45 CFR 46 that a research project or activity involving human subjects has been reviewed and approved by the IRB in accordance with an approved assurance on file with OPRR. Certification is required when the research is funded by DHHS and not otherwise exempt in accordance with 45 CFR 46.

8. Minimal Risk - the risks of harm anticipated in the proposed research which are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

9. Expedited Review - a review that may be performed in accordance with 45 CFR 46 by delegation from the IRB to the "IRB chairperson or an experienced reviewer for research procedures" that would involve no more than minimal risk. Minor changes in previously approved research may also be given expedited review during the period for which approval is authorized. OPRR maintains and updates as appropriate a list of categories of research that may be reviewed by the IRB through an expedited review procedure.

10. Multiple Project Assurance List (M.P.A.L.) - A list of institutions pledging compliance with DHHS regulations. (Issued periodically by the Office for Protection from Research Risks.)

11. Applications Lacking Definite Plans for Involvement of Human Subjects (45 CFR 46.118) - Certain types of applications are submitted with the knowledge that subjects may

be involved within the period of support, but definite plans would not normally be set forth in the application. Examples would be involvement depending upon completion of instruments, prior animal studies, etc.

12. Performance Site - A performance site is usually considered engaged in research when its staff or private records of identifiable individuals are utilized in the conduct of the research. Solicitation of consent by site staff would be considered engagement.

Policy

CDC policy is that no research activity involving human subjects unless specifically exempt under 45 CFR 46 or waived shall be supported by CDC until the requirements of 45 CFR 46 and this policy have been met. While the responsibility for the determination that all such requirements are met and that the rights and welfare of human subjects have been and will be adequately protected resides at **all levels of institutional and CDC** review.

Identification of Responsibilities

1. Institutional Responsibilities

a. General

The grantee has primary responsibility for safeguarding the rights and welfare of human subjects in research conducted at or sponsored by the grantee. Grantee documentation of assurances of compliance with, and implementation of, the regulations for the protection of human subjects, when approved by OPRR, established accountability of this responsibility.

b. IRB Review of Research

As provided in 45 CFR 46:

(1) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove provisions for safeguarding the rights and well being of human subjects in all research activities covered by the regulations.

(2) An IRB shall require that information given to subjects as part of the process of obtaining informed consent is in accordance with 45 CFR 46. The IRB may require that information, in addition to that specifically mentioned in the regulations, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

(3) An IRB shall require documentation of informed consent or may waive documentation in accordance with the regulations.

(4) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

(5) An IRB shall conduct continuing review of research covered by the regulations at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

c. Declaration or Certification

Submission of a validly dated Optional Form 310 is required for **all** non-exempt research involving human subjects. A validly dated Optional Form 310 is one on which the reported IRB certified approval date is no earlier that one year before the receipt date for which the application is submitted. When an exemption* is designated on the face page of an application (Form 398 for example), Optional Form 310 is not required, but sufficient information must be provided in the

application in the narrative discussion of human subjects involvement to allow a determination that the designated exemption is appropriate.

(*Note: If an application is to be funded, the CDC Deputy Associate Director for Science must confirm this exemption. The procedure is addressed later in this document.)

If certification is delayed by an institution with a valid assurance, an additional filing of Optional Form 310 (or a letter from the IRB Chairperson) is required. This certification should be received within 60 days after the receipt or deadline date for which the application was submitted or three weeks before the objective review group meets, whichever comes sooner. In the absence of certification, the application must be considered incomplete. Institutions without valid assurances must also declare their intention to comply with 45 CFR Part 46 as provided on Optional Form 310.

2. Office for Protection from Research Risks (OPRR) Responsibilities

OPRR has Department-wide authority and responsibility for implementing 45 CFR 46, including: interpretation of the regulations; negotiation of assurances of compliance, and other matters relating to the assurance filed by grantee institutions; and providing clarification and guidance with respect to ethical issues raised in connection with research involving human subjects:

(a) Negotiates assurances with institutions seeking grants in support of research with human subjects. (Coordinates with the Grants Management Branch, CDC)

(b) Assists and advises CDC concerning involvement of human subjects in research activities.

(c) Investigates possible instances of noncompliance with DHHS policy.

(d) Periodically issues a Multiple Project Assurance List of institutions that have

filed assurances with general applicability.

3. CDC Responsibilities

In accordance with 45 CFR Part 46, CDC will review all applications involving human subjects for compliance with the regulations. Review will be conducted by CDC staff. Applications involving human subjects will be evaluated by objective review group (ORG) members. The evaluation will consider the risks to subjects, the adequacy of the protection against the risks, potential benefits of the proposed research to the subjects and others, and the importance of the knowledge to be gained.

It may be necessary to review the informed consent form to be used in connection with a project. The pertinent CIO official may request the form.

a. CDC Deputy Associate Director for Science Responsibilities

There is a designated coordinator for CDC who works with the CIO Associate Directors for Science and/or the Human Subjects Contacts. The Deputy Associate Director for Science:

(1) Maintains liaison with OPRR.

(2) Provides CIO and GMB staffs with information about the DHHS human subjects regulations.

(3) Assists and advises CIO and GMB staff on human subjects problems.

(4) Reviews Program Announcements and advises CIO and GMB staffs regarding applicability of the human subjects regulations to the projects that will be funded under the program.

(5) Determines and documents whether research to be funded is exempt from IRB

review.

b. Centers, Institute, Offices (CIOs)

Each CIO is responsible for designating a Human Subjects Contact. The Human Subjects Contact, who serves as the CIO expert and lead on implementing the 45 CFR 46, is responsible for the following:

(1) Determines and documents whether activities are research or non-research.

(2) Determines and documents whether research involves human participants.

(3) Identifies to the CIO, when preparing Program Announcements, whether projects funded could involve humans as participants and indicates when CDC investigators will be involved in conducting the research. Confirms that all appropriate human participants language is included in the Program Announcements.

(4) Reviews and clears all protocols for IRB review when CDC investigators are involved in conducting the research.

(5) Advises objective review group members of their responsibilities regarding review of grant/cooperative agreement applications involving human participants.

(6) Reviews applications to be funded for human participants designation, appropriateness of exemptions, and adequacy of information provided. Signs the "Tracking Form for Contracts, Purchase & Task Orders, Modifications to Contracts, and for New, Renewal, and Noncompeting Continuation Grants and Cooperative Agreements" that must be submitted with funding memoranda.

The CIO:

(1) Follows up with applicants whenever designation is inappropriate or human participants-related information is lacking.

(2) Notifies GMB of any special restrictions in research procedures.

(3) Monitors for changes in human participants involvement and projects without definite plans for human participants involvement (e.g., training grants).

c. Grants Management Branch Responsibilities

(1) Reviews application and documents that required assurances and certifications are in place.

(2) Follows up with applicant for missing documentation.

(3) Reviews documentation on research proposals where the research involves human participants.

(4) Follows up with CIO officials if discrepancies exist.

(5) If an exemption is claimed on the "Tracking Form for Contracts, Purchase & Task Orders, Modifications to Contracts, and for New, Renewal, and Noncompeting Continuation Grants and Cooperative Agreements" provided by the CIO, GMB promptly forwards it to the Deputy Associate Director for Science for concurrence.

(6) Requests OPRR to negotiate single project assurances where required.

Implementation

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1. Program Announcements

For those programs involving research where humans are expected to be participants, the CIO under advisement from the CIO HSC, must make certain the following language is included in the Human Subjects subpart of the Other Requirements section in the Program Announcement:

"If the proposed project involves research on human participants, the applicant must comply with the Department of Health and Human Services Regulations (45 CFR 46) regarding the protection of human research participants. Assurance must be provided to demonstrate that the project will be subject to initial and continuing reviews by an appropriate institutional review board. The applicant will be responsible for providing evidence of this assurance in accordance with the appropriate guidelines and forms provided in the application kit.

In addition to other applicable committees, Indian Health Service (IHS) institutional review committees also must review the project if any component of IHS will be involved with or will support the research. If any American Indian community is involved, its tribal government must also approve that portion of the project applicable to it.

Unless the awardee holds a Multiple Project Assurance (MPA), a Single Project Assurance (SPA) is required, as well as an assurance for each subcontractor or cooperating institution that is engaged in the research.

OPRR negotiates assurances for all activities involving human participants that are supported by the DHHS."

If CDC scientists will be co-investigators in the research project (e.g., assist in the design of the study, assist in the design of the instruments, assist in the development of methods and procedures for the study, assist in the analysis of the data/specimens, assist in the interpretation of the data, or co-author a paper), the

HSC must make certain the following insert related to obtaining CDC IRB approval is included in the CDC Activities listed under the Program Requirements section in the program announcement:

" Assist in the development of a research protocol for IRB review by all institutions participating in the research project.

The CDC IRB will review and approve the protocol initially and on at least an annual basis until the research project is completed."

To verify that the HSC has reviewed the Program Announcement and included all appropriate language in the announcement if humans are expected to be participants in the research, the HSC must sign the certification of available funds document (CDC 0.1067 form) which must be submitted to GMB when the final version of the Program Announcement is submitted.

2. Assurances and Certifications

(a) During the initial administrative review of the application by GMB, the application checklist must be reviewed for the use of human subjects. A certification Optional Form 310 (or designation on the application form 398) must be provided with the application if humans are involved (whether or not the research is exempt). If certification is not provided, GMB must request it from the applicant.

Prior to review of the application by the objective review group, the CIO official responsible for the review must determine that all human subjects information has

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or the subjects. The CIO official or HSC

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must also advise the ORG members of the

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irresponsibility to evaluate the prot

ection of the subjects.

(b) Applications Lacking Definite Plans for the Involvement of Human Subjects:

Certain types of applications for grants are submitted to CDC with the knowledge that subjects may be involved within the period of funding but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants where selection of specific projects is the institution's responsibility; research training grants where the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by an IRB before an award can be made. However, except for research exempted or waived under the

regulations (45 CFR 46), no human subjects may be involved in any project supported by the award until the project has been reviewed and approved by an IRB (following the regulations, and certification submitted to GMB).

3. Review of Applications by the Objective Review Group

The objective review group is expected to review the human subjects protocol in the application (if applicable). The review will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the proposed research to the subjects, and the importance of the knowledge to be gained.

For applications involving human participants, the objective review group may recommend:

(a) Approval of the application without any human subjects restrictions;

(b) Approval of the application but with comments made to the applicant regarding human subjects protections;

(c) Limitations of the work proposed, the imposition of restrictions, the elimination of concerns relating to the protection of human subjects prior to the release of an award; or

(d) Disapproval of the application if the research risks are sufficiently serious and protection against the risks is so inadequate as to make the entire application unacceptable.

4. Preparation of Summary Statements

A section must be provided in the Summary Statement reflecting the ORG's evaluation of the use of the human subjects. If there are any restrictions, limitations, concerns and comments relating to the human subjects, they must be

addressed in the Summary Statement.

5. Pre-Award Review by CIO Officials

The CIO Officials must review each application to determine, prior to award of a grant, that all human subjects concerns and protections which appear inadequate as noted by the ORG are satisfactorily resolved. All restrictions, concerns, etc. regarding the human subjects should be transmitted in writing to the official signing for the institution, with a copy to the principal investigator. The response, if adequate, should be submitted to the Grants Management Branch with the funding memorandum indicating that all concerns have been adequately addressed. The CIOs must attach to the funding memorandum the "Tracking Form for Contracts, Purchase & Task Orders, Modifications to Contracts, and for New, Renewal, and Noncompeting Continuation Grants and Cooperative Agreements" which indicates whether humans will be participating as subjects in the proposed research award. The form will also identify if CDC scientists will be co-investigators; and if so, whether the CDC IRB has reviewed and approved the protocol. The form is to be signed and dated by the HSC.

6. Review and Award by the Grants Management Branch

(a) Pre-award Review of Applications

When the CIOs submit funding memoranda for new and continuation awards, they must attach to the memorandum, the "Tracking Form for Contracts, Purchase & Task Orders, Modifications to Contracts and for New, Renewal, and Noncompeting Continuation Grants and Cooperative Agreements" which indicates whether humans will be participating as subjects in the proposed research award. The form will also identify if CDC scientists will be co-investigators; and if so, whether the CDC IRB has reviewed and approved the protocol. The form is to be signed and dated by the HSC. If an exemption is claimed under 46.101, GMB will promptly forward the Tracking Form and a copy of the application to the Deputy Associate Director for Science for concurrence.

Before a year has elapsed between the IRB review date certified on the Optional Form 310 and the anticipated award date, GMB must require IRB re-review and certification by a validly dated Optional Form 310 prior to award.

All applications having unresolved human participants concerns must have documentation from the CIO of the satisfactory resolution of the human participants concerns. If this is not possible prior to award, information regarding any restrictions must be transmitted in writing on the Tracking Form to GMB for inclusion on the award notice.

Where the research will be conducted by cooperating institutions, all of the cooperating institutions must have filed Assurances of Compliance with OPRR and evidence of IRB review and approval (including CDC, if CDC scientists are involved in the projects as investigators).

For all research awards involving humans as participants, GMB will enter one or more of the following codes into the award module of the Grants Management Information System (GMIS):

30 - human subjects - one site
33 - human subjects - multiple sites
36 - human subjects - multiple sites including CDC as one of the sites

40 - awardee missing an assurance or certification
41 - awardee missing an assurance or certification and application lacks definite research plans
43 - any of the participating sites missing assurances or certifications
46 - certification missing for CDC
49 - human subjects concern(s) expressed by ORG, requires resolution

These codes serve as reminders that the project involves humans as participants and that annual IRB reviews and monitoring are required in order to comply with the human subjects regulations.

We are encouraged to review our portfolios for those activities that may be funded and involve human subjects. Prompt submission of necessary information to OPRR, as soon as it is known that an award is likely to be made, may enable successful negotiation and approval of an Assurance prior to funding component deadlines.

Application with Definite Plans for Research and Awardee Missing an Assurance

For each application recommended for approval which is likely to be funded and which requires negotiation of an Assurance of Compliance (when the institution is not listed on the Multiple Project Assurance List), GMB will forward to the OPRR Assurance Coordinator at the appropriate time a request for negotiation of an assurance of compliance using OPRR's designated format (attached to this document). The following should be attached to the request: the section of the application containing the research plan, summary statement, addenda, and information identifying the individual(s) at CDC who should be notified when the negotiation is completed and the assurance approved. OPRR will notify CDC of the approval of a satisfactory assurance.

Application with Definite Plans for Research and Foreign Awardee Missing an Assurance

For applications involving human participants from (1) foreign/international organizations (without an assurance of compliance) who are conducting research involving humans as the subjects; (2) foreign organizations (with or without an assurance of compliance) who are conducting research involving humans participants and their foreign subcontractors (without assurances of compliance) are participating in the research; and (3) domestic institutions (with or without assurances of compliance) who are subcontracting with a foreign/international organization (without an assurance of compliance) that is participating in the research, GMB must submit the following information to the Deputy Associate Director for Science via interoffice mail:

1. The GMB contact's name, title, telephone number, and mailstop.
2. The applicant organization's name, address, telephone number for the individual who signed the application, and the application/contract number.
3. Names and locations of all participating organizations.
4. Clear indication for applicant and each participating organization as to whether it has an assurance of compliance.
5. The project title and projected budget period start date.
6. The Program Announcement number.
7. Name, telephone number, and mailstop for the CDC Program Official.
8. Copy of the application.

The Deputy Associate Director for Science will inform the grants office via telephone if any participating organizations might already have special assurances on record and provide the assurance numbers. If there is no assurance on record, the Deputy Associate Director for Science will request it, and send a copy of the request to GMB. It will be the responsibility of the grants office to code awards appropriately and track the receipt of the assurances.

Application with Definite Plans for Research; the Awardee Missing an Assurance; and There is Insufficient Time to Obtain an Assurance Prior to Award (September Awards)

When there is insufficient time to obtain an assurance of compliance for an award with definite research plans before the award must be made to meet CDC's award deadlines, OPRR has agreed to allow the release of the award with restrictions (language for the restriction provided by OPRR) on the use of funds for research involving humans. Restricted awards can be released **only after** OPRR is informed and has taken appropriate action in response. The request to OPRR for the single project assurance should contain the following paragraphs (see attached FAX format):

"Because there is insufficient time to obtain the single project assurance before the award must be made to meet CDC's award deadline, CDC requests your approval to issue the award with the following restrictive language:

Notice: Under governing regulations, Federal funds administered by the Department of Health and Human Services shall not be expended for research involving human subjects, and individuals shall not be enrolled in such research, without prior approval by the Office for Protection from Research Risks of an assurance to comply with the requirements of 45 CFR 46 to protect human research subjects. This restriction applies to all collaborating sites without OPRR-approved assurances, whether domestic or foreign, and compliance must be ensured by the awardee."

OPRR will accept the **FAX document without the usual supporting materials with the clear understanding that GMB will forward them within the first week of the new fiscal year.**

Upon receipt of GMB's FAX, OPRR will record the restriction in its computer records and fax back acknowledgment to GMB. If a request for restriction is sent to OPRR by e-mail, OPRR's response will be by e-mail. GMB will accept OPRR's e-mail records as the equivalent of signed faxes.

When the section of the application that describes the research plan, summary statement, and any other supporting materials are submitted to OPRR within the first week of the new fiscal year, they should be accompanied by the memo requesting negotiation of the assurance(s) and a copy of the FAX document signed by OPRR.

Application Lacking Definite Plans for Research and Awardee Missing an Assurance

If an application lacks definite plans for the involvement of human subjects, a restricted award may be issued but only following approval by OPRR. The request

to OPRR may be submitted via FAX using the attached OPRR FAX Transmission document without the application and summary statement. The FAX document indicates to OPRR that CDC will place the following restriction on the award:

> Notice: Without prior approval by the Office for Protection from Research Risks (OPRR) of an assurance to comply with the requirements of 45 CFR 46 to protect human research subjects, Federal funds administered by the Department of Health and Human Services shall not be expended for research involving human subjects, and individuals shall not be enrolled in such research. This restriction applies to all collaborating sites without OPRR-approved assurances, whether domestic or foreign, and compliance must be ensured by the awardee.
>
> CDC is notifying OPRR to provide you with a single project assurance application. As soon as your protocol is developed, submit it to the CDC Grants Management Officer (GMO) and forward it along with your completed single project assurance application to OPRR.
>
> When OPRR notifies you of approval of a single project assurance, provide the GMO with completed Protection of Human Subjects Assurance Identification/Certification/Declaration forms (Optional Form 310) for every performance site involved in your project.

OPRR will sign and fax back acknowledgment to GMB.

For cooperative agreement projects in which CDC investigators are involved as co-investigators, the CIO Program Official must send a revised tracking form to GMB reflecting approval of the research protocol by the CDC IRB.

Review and Award of Noncompeting Continuation Application

GMB will ascertain the presence and completeness of the Optional Form 310 or designation on the application form 2590. Certification must be within 12 months

preceding the requested award date. No award may be made until a proper certification is received by GMB. The CIO Program Official must submit a completed Tracking Form along with the funding documentation.

Research Where the CIO HSC or the Awardee Claims an Exemption

All determinations that research is exempt from IRB review **must** be reviewed and approved by the Deputy Associate Director for Science. This includes determinations made by CIO HSCs, by awardee IRBs, or by other participating organization IRBs. The Tracking Form must be completed, signed, and dated by the HSC. Upon receipt, GMB will promptly send the Tracking Form and application to the Deputy Associate Director for Science by interoffice mail for concurrence. (At the end of the fiscal year, when time is limited for issuing awards, GMB may request the Deputy Associate Director for Science to review the applications in the GMB offices rather than sending the application.)

Special Circumstances:

If a CIO does not provide all the required human subjects information to GMB, GMB will assume that any proposed activity involving data collection and/or analysis is research and CDC investigators are participating in the study and the project is therefore subject to the human subjects regulations.

Disagreements between a CIO HSC and GMB involving whether research is subject to the human subjects regulations or whether the project is exempt from IRB review, etc. will be resolved by the Deputy Associate Director for Science who should be contacted immediately by either party by e-mail, telephone, or memorandum with notification to the other party.

Attachments:

(1) Tracking Form for Contracts, Purchase & Task Orders, Modifications to Contracts, and for

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New, Renewal, and Noncompeting Continuation Grants and Cooperative Agreements
(2) Request format for OPRR to negotiate a Single Project Assurance
(3) Request format (FAX) to OPRR to negotiate a Single Project Assurance when there is insufficient time to obtain one prior to issuance of an award.
(4) Request format (FAX) to OPRR to request permission to issue a restricted award for projects with indefinite plans for involvement of human subjects.
(5) Assistance Request Grants and/or Cooperative Agreements (certification of available funds) CDC Form 0.1067 (This is a Jetform)
(6) OPRR Memorandum Regarding Restricted Awards

Revised:
July 16, 1998; September 23, 1998; January 5, 1999; January 25, 1999, March 9, 1999, March 23, 1999; May 11, 1999; May 12, 1999

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BRIEF SUMMARY
ROLES AND RESPONSIBILITIES

1. CIO Officials

   a. identify in the Program Announcement whether projects funded could involve humans as subjects.

   b. review application for human subjects designation, appropriateness of exemptions, adequacy of information provided;

   c. follow up with applicant whenever designation is inappropriate or human subjects-related information is lacking;

   d. brief ORG members regarding review of the human subjects protocol;

   e. prepare Summary Statement with paragraph on human subjects;

   f. resolve concerns with applicants to be funded;

   g. review applications to be funded for human participants designation, and adequacy of information provided. Signs the "Tracking Form for Contracts, Purchase & Task Orders, Modifications to Contracts, and for New, Renewal, and Noncompeting Continuation Grants and Cooperative Agreements" that must be submitted with funding memoranda. Notify GMB of any special restrictions in research procedures.
   h. monitor for changes in human subjects involvement, and projects without definite plans for human subjects involvement (e.g., training grants).

2. ORG

   a. reviews human subjects protocol;

   b. reaches agreement on recommendation on human subjects protections

3. Grants Management Branch

    a. reviews documentation in grant files;

    b. follows up with CIO Officials if discrepancies exist;

    c. documents that assurances and certifications are in place;

    d. requests single project assurances where required.